

Inventor: Staub, et al.
Attorney Docket No.: 34411-5
Express Mail No. EJ018233725US

WHAT IS CLAIMED IS:

1. A method for ensuring that a newborn/mother pairing is correct at discharge, said method comprising:
 3. a. obtaining a first sample of newborn cells at the birth of a newborn;
 4. b. storing said first sample on a tamper-proof collection device;
 5. c. forwarding said tamper-proof collection device to a genotyping location; and
 6. d. examining said tamper-proof collection device to ensure that tampering has not occurred.
 7. e. genotyping said first sample to provide a first newborn fingerprint;
 8. f. obtaining a second sample of newborn cells from said newborn prior to discharge in accordance with steps b, c and d;
 9. g. genotyping said second sample to provide a second newborn fingerprint; and
 10. h. comparing said first and second newborn fingerprints, wherein substantial identity of the first and second newborn fingerprints indicates that said newborn has not been switched prior to discharge.
1. 2. The method of claim 1, further comprising the step of storing said tamper-proof collection device for possible future use.

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- 1 3. A method as in claim 1, wherein said sample of newborn cells is obtained from a buccal swab, blood, cord blood, amniotic fluid, embryonic tissue, hair, skin, or fingernail clipping.
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- 1 4. A method as in claim 1, further comprising the steps of:
 - 2 a. obtaining at least one sample of maternal cells from a mother in accordance with steps b, c and d of claim 1;
 - 3
 - 4 b. genotyping said sample of maternal cells to provide a maternal fingerprint; and
 - 5 c. comparing said maternal fingerprint and said first or second newborn fingerprints,
6 wherein about 50% identity between the maternal fingerprint and the first or
7 second newborn fingerprints indicates that the newborn/mother pairing is
8 correct.
 - 1 5. The method of claim 1, further comprising the step of generating a report comprising a
2 summary of said comparison.
 - 1 6. The method of claim 4, further comprising the step of generating a report comprising a
2 summary of said comparisons.
 - 1 7. A method for ensuring that a newborn and a mother are related at discharge, said method
2 comprising:

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- 1 a. obtaining discharge-samples of newborn cells from a newborn and maternal cells
2 from a mother prior to discharge;
 - 3 b. genotyping said discharge-samples to provide a discharge newborn fingerprint and
4 a discharge maternal fingerprint;
 - 5 c. comparing said discharge newborn fingerprint and said discharge maternal
6 fingerprint, wherein about 50% identity indicates that said newborn and said mother
7 are related.
- 13 8. The method of claim 7, comprising the further step of:
- 2 a. obtaining a birth-sample of newborn and maternal cells at the birth of said newborn;
 - 3 b. genotyping said birth-samples to provide a birth newborn fingerprint and a birth
4 maternal fingerprint;
 - 5 c. comparing said birth newborn fingerprint, said discharge newborn fingerprint, said
6 birth maternal fingerprint, and said discharge maternal fingerprint,
7 wherein substantial identity between the birth newborn fingerprint and
8 discharge newborn fingerprint and substantial identity between the birth
9 maternal fingerprint and discharge maternal fingerprint confirm that the
10 samples have not been tampered with; and
11 wherein 50% identity between the newborn fingerprints and the maternal
12 fingerprints confirm that the newborn and mother are related.

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- 1 9. The method of claim 7, further comprising the following steps:
- 2 a. storing said discharge-samples on a single tamper-proof collection device;
- 3 b. forwarding said tamper-proof collection device to a genotyping location;
- 4 c. examining said tamper-proof collection device to ensure that tampering has not occurred.
- 1 10. The method of claim 8, further comprising the following steps:
- 2 a. storing said discharge-samples and said birth-samples on two or fewer tamper-proof collection devices;
- 3 b. forwarding said tamper-proof collection devices to a genotyping location;
- 4 c. examining said tamper-proof collection devices to ensure that tampering has not occurred.
- 1 11. The method of claim 9, further comprising the step of retaining said tamper-proof collection device for future use.
- 1 12. The method of claim 10, further comprising the step of retaining said tamper-proof collection devices for future use.

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- 1 13. The method of claim 7, wherein said sample of newborn cells is obtained from a buccal
2 swab, blood, cord blood, amniotic fluid, embryonic tissue, hair, skin or fingernail clipping
3 and wherein said sample of maternal cells is obtained from blood, buccal swab, hair or
4 fingernail clippings.
- 1 14. The method of claim 8, wherein said sample of newborn cells is obtained from a buccal
2 swab, blood, cord blood, amniotic fluid, embryonic tissue, hair, skin or fingernail clipping
3 and wherein said sample of maternal cells is obtained from blood, buccal swab, hair or
4 fingernail clippings.
- 1 15. The method of claim 7, wherein said sample of newborn cells and maternal cells are obtained
2 from a buccal swab.
- 1 16. The method of claim 8, wherein said sample of newborn cells and maternal cells are obtained
2 from a buccal swab.
- 1 17. The method of claim 7, wherein said discharge-samples of newborn cells and maternal cells
2 are selected from the group consisting of separate samples, mixed samples, or separate
3 samples and a mixed sample.
- 1 18. The method of claim 8, wherein said discharge-samples of newborn cells and maternal cells

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1 are selected from the group consisting of separate samples, mixed samples, or separate
2 samples and a mixed sample.

1 19. The method of claim 7, further comprising the step of generating a report comprising a
2 summary of said comparison.

1 20. The method of claim 8, further comprising the step of generating a report comprising a
2 summary of said comparisons.

1 21. An improved sample collection device for use in identifying newborn/mother pairs, said
2 device comprising:

- 3 i. a location and label for a maternal cell sample,
4 ii. a location and label for a newborn cell sample;
5 iii. optionally, a location and label for a mixed newborn and mother cell sample;
6 and
7 iv. optionally, a location and label for a paternal cell sample.
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1 22. The sample collection device of claim 4, wherein the device is selected from the group
2 consisting of a Guthrie card, a trifold collection card, a bifold collection card, paper, slide,
3 tube or container.

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